DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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[Docket No. 01N–0397]

Transportation Safety and Potentially Sedating or Impairing Medications; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to gather data on the potential public health consequences related to sedating or impairing medications. This meeting will be jointly sponsored with the National Transportation Safety Board (NTSB). The meeting will be held to determine what data are available to define the role of sedating or impairing medications in accidents and related injuries, how the potential for medications to cause impairment might be best assessed, and how this risk would be most effectively communicated to the public.

DATES: The meeting will be held on November 14, 2001, from 8 a.m. to 5 p.m. and November 15, 2001, from 8 a.m. to 4 p.m. Persons desiring to make oral presentations during the meeting must register by October 17, 2001. Submit written or electronic comments by December 17, 2001.

ADDRESSES: The public meeting will be held at the National Transportation Safety Board (NTSB) Board Room, 429 L'Enfant Plaza, SW., Washington, DC 20594. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

Registration: Submit registration information by close of business on October 17, 2001, electronically at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm.

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Once on this Internet site, select Docket No. 01N–0397 and follow the directions. Submit registration information by mail to Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee Lemley or Anne M Food and Drug Administration,. Henig, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, 301–594–6779, e-mail: lemleyl@cder.fda.gov or heniga@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information

Why is FDA/NTSB holding this meeting?

FDA/NTSB is holding this joint meeting in response to NTSB Safety Recommendation I–00–5, requesting that FDA (1) Establish a clear, consistent, easily recognizable warning label for all prescription and over-the-counter medications that may interfere with an individual's ability to operate a vehicle and (2) require that the label be prominently displayed on all packaging of such medications.

On what issues does FDA seek comment?

- What data are available to show that sedating or impairing medications contribute to accidents?

- If data are available, can the public health impact of any such effect be delineated? · What type of testing would best define the potential for a medication to contribute to accidents? Are there validated test methods for assessing the degree of risk associated with the use of medications that are sedating or impairing?

- What would be the most effective manner of communicating the risk of performance impairment (e.g., labeling, pictogram, educational programs, or other manner of communication)?

- What is the experience of other institutions (local, national, and international; public and private) in assessing, communicating, and preventing the risk of sedating or impairing medications in vehicle operators? How are currently applicable laws and regulations enforced?

II. Registration and Requests to Make Oral Presentations

If you would like to make an oral presentation during the meeting, you must register by close of business on October 17, 2001, either electronically or by mail (information above). There is no registration fee, but you must register. You must provide your name, title, business affiliation (if applicable), address, telephone number, fax number, e-mail address, and the type of organization you represent (e.g., industry, consumer organization). Registered persons should check in before the meeting. Persons requiring a sign language interpreter or other special accommodations should notify Lee Lemley or Anne M. Henig at 301–594–6779 by October 31, 2001.

If you are making an oral presentation during the meeting, you must indicate this on your registration form and submit: (1) A brief written statement of the general nature of the views you wish to present and (2) the names and addresses of all persons who will participate in the presentation.

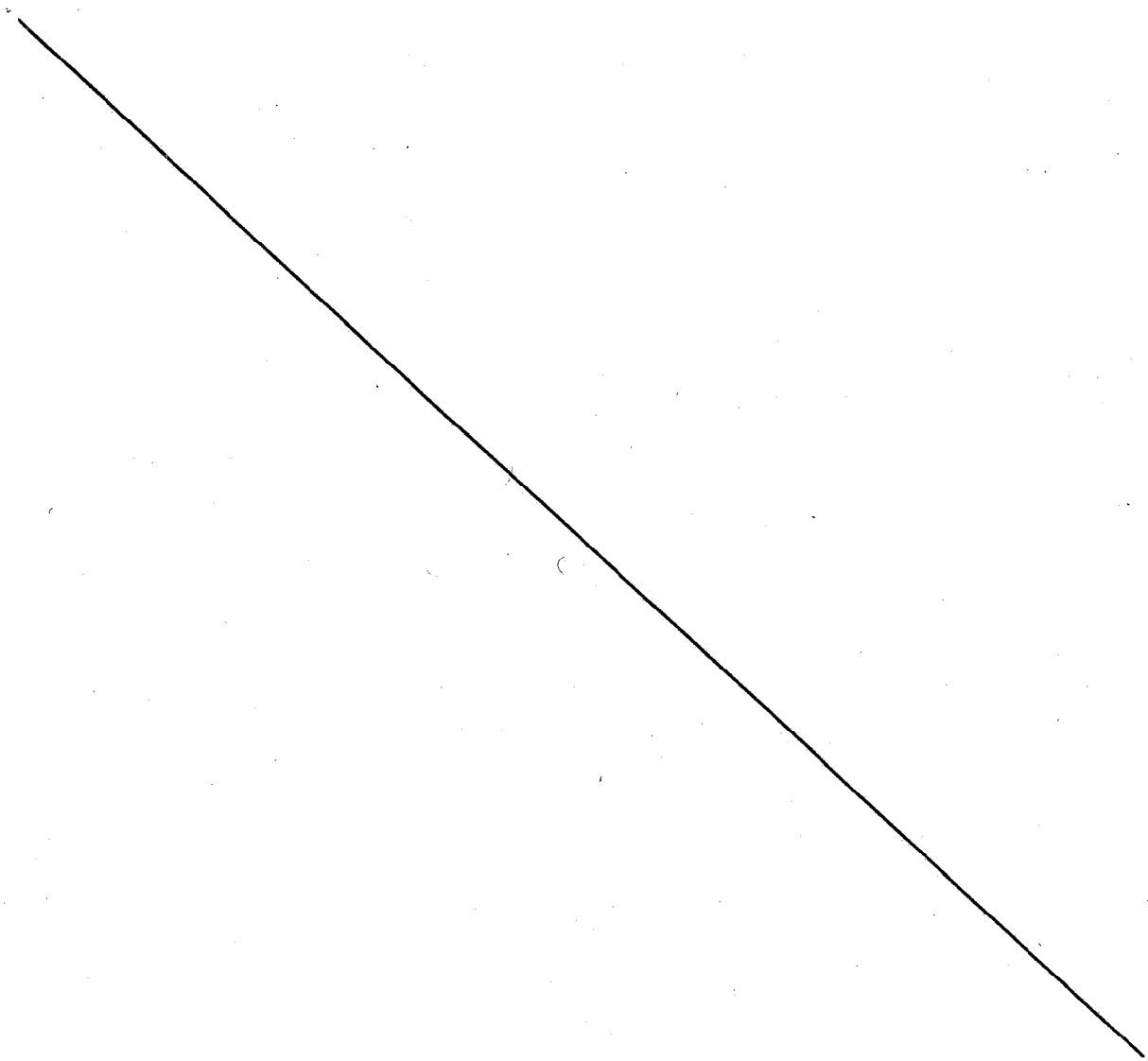
Depending on the number of people who register to make presentations, we will limit the time allotted for each presentation (from 3 to 5 minutes). It is anticipated that, during the meeting, persons attending the meeting will have the opportunity to ask questions through question cards that will be handed out.

III. Comments

Interested persons may submit to the Dockets Management Branch (addresses above) written or electronic comments regarding the topics addressed at the public meeting by December 17, 2001. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Transcripts

You may access a copy of the transcript on the FDA Internet site at http://www.fda.gov, request a transcript of the meeting from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the meeting, at a cost of 10 cents per page, or examine a transcript of the meeting



after December 17, 2001, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9-18-01

September 18, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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